RPM Plus Regional Training Course on Pharmaceutical Management for Malaria, East Africa

Dar es Salaam, Tanzania, November 28– December 2, 2005:

Workshop Report

Management Sciences for Health
is a nonprofit organization
strengthening health programs

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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CONTENTS

ACRONYMS

ACT	artemisinin-based combination therapy
ADR	adverse drug reaction
CMD	Community Medicine Distributor
DRC	Democratic Republic of Congo
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
IPT	intermittent preventative therapy
MMSS	Malaria Medicines and Supply Service
MSD	Medical Stores Department
MSH	Management Sciences for Health
NGO	nongovernmental organization
NMCP	National Malaria Control Programme
PDA	portable digital assistant
RBM	Roll Back Malaria
RDT	rapid diagnostic test
RPM Plus	Rational Pharmaceutical Management Plus (Program)
SP	sulfadoxine-pyrimethamine
STGs	standard treatment guidelines
TFDA	Tanzania Food and Drug Administration
TLC	thin-layer chromatography
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization

ACKNOWLEDGMENTS

EXECUTIVE SUMMARY

The Regional Training Course on Pharmaceutical Management for Malaria held in Dar es Salaam, Tanzania, from November 28 to December 2, 2005, provided a forum for major stakeholders from 10 country and territory Malaria Control and Essential Drug Programs, central medical stores, and departments of pharmacy to develop their capacity to manage medicines and supplies for national malaria control programs. Participants attended the course from Burundi, Democratic Republic of Congo (DRC), Ethiopia, Kenya, Madagascar, Rwanda, Tanzania, Uganda, Zambia, and Zanzibar. The course provided information and hands-on practice to facilitate national program managers' understanding and implementation of basic pharmaceutical management concepts and methods, plus the process of monitoring the implementation process with respect to pharmaceutical management.

Workshop materials focused on pharmaceutical management for malaria, particularly the selection and quantification of antimalarials, procurement, distribution, quality assurance, rational use, and monitoring and evaluation. Participants learned practical approaches for applying key concepts in monitoring the pharmaceutical management cycle. Because so many East African countries have recently adopted and are moving toward implementing new malaria treatment policies, monitoring and evaluation to inform implementation processes and the roll out of artemisinin-based combination therapy (ACT) policy in those countries was highlighted throughout the course. By the end of the course, participants were able to understand basic theories, apply them, and establish mechanisms for managing antimalarials and related supplies and also identify key performance indicators for monitoring implementation of malaria case management programs.

The workshop consisted of presentations, discussions, and group exercises. The design was highly participatory, and the exchange of skills and experience among participants added valuable depth to the learning process. The workshop was conducted in English with French interpretation, and course materials were made available in English and French. Course materials were developed by the Rational Pharmaceutical Management (RPM) Plus Program.

In addition, country program managers developed national improvement plans for pharmaceutical management to use as advocacy tools in support of partners for achieving desired ACT implementation goals. These plans will also be used as a basis for follow-up in countries in which RPM Plus has a presence to measure the effect of the course and to monitor progress in achieving the milestones and outcomes set by the participants.

The course provided a rich source of information for building RPM Plus regional technical activities supporting malaria control. The course evaluation by participants is included in the appendix and demonstrates that this approach in building regional capacity in pharmaceutical management is beneficial to countries.

INTRODUCTION

Background

The Regional Training Course on Pharmaceutical Management for Malaria for the East and Southern African region took place from November 28 to December 2, 2005, at the Movenpick Royal Palm Hotel in Dar es Salaam, Tanzania. Thirty-five participants attended the training course. Attendees came from malaria programs, essential medicines programs, pharmacy departments, procurement departments, and central medical stores in 10 malaria-endemic countries and territories in the East and Southern African regions. Participants were from Burundi, Democratic Republic of Congo (DRC), Ethiopia, Kenya, Madagascar, Rwanda, Tanzania, Uganda, Zambia, and Zanzibar. Participants from Malawi were invited but had to cancel their participation at the last minute. Additional organizations represented included the World Health Organization (WHO) Tanzania country office, Malaria Medicines and Supply Service (MMSS) of the Roll Back Malaria (RBM) Partnership, and the U.S. Agency for International Development (USAID) Mission to Tanzania.

The overall goal of the course was to build regional capacity and increase knowledge and awareness of the elements of pharmaceutical management that affect access and rational use of antimalarial medicines.

The course was organized by the RPM Plus Program of Management Sciences for Health (MSH) in collaboration with the Tanzanian National Malaria Control Programme (NMCP); the MSH Tanzania country office; the Office of the Chief Pharmacist, Ministry of Health of Tanzania; and USAID.

Rationale for the Training Course

More than 80 percent of the clinical cases of malaria each year occur in Africa, with much of the burden in children under five years of age. The landscape of malaria chemotherapy is further complicated by growing parasite resistance to commonly used first-line therapies. As a result, WHO recommends that countries changing their first-line therapy should opt for the more effective artemisinin-based combination therapies (ACTs); consequently, many countries in the region are at various stages of implementing the policy change. However, there hasn't been much experience with ACTs in African malaria programs. Furthermore, the medicines are expensive—approximately 25–50 times more costly than the older generation of antimalarials and have a short half-life. These properties put more pressure on endemic countries to take a systematic approach to antimalarial medicine supply.

To develop national and regional level capacity to address pharmaceutical management issues of new antimalarial therapies within the East and Southern Africa regions, RPM Plus, in partnership with the NMCP, Ministry of Health of the Republic of Tanzania; the Malaria Action Coalition; and the USAID Mission to Tanzania, conducted this regional training course on pharmaceutical management for malaria.

Training Course Objectives and Expected Outcomes

The objectives of the training course were to—

- Apply appropriate criteria and select necessary first- and second-line medicines and supplies for national programs, taking into consideration WHO recommendations

- Apply good procurement practices to antimalarial medicines

- Select an appropriate method for quantification, identify appropriate sources for data, and carry out an estimation of antimalarial medicine needs using the method selected

- Establish technical specifications and appropriate mechanisms of supply to assure the quality of medications and commodities procured and used in national programs

- Establish the appropriate mechanisms to guarantee that medicines and supplies are distributed to health services at the right moment and in adequate quantities

- Establish appropriate mechanisms for ensuring rational use of antimalarial medicines

- Establish monitoring mechanisms for availability and use of antimalarials

The expected outcomes of the training course were to—

- Apply appropriate criteria in the selection of first- and second-line medicines and supplies

- Apply good practices for the procurement of antimalarial medicines

- Increase capacity for conducting an estimation of antimalarial medicine needs using appropriate methods and sources of data

- Apply appropriate mechanisms for assuring quality of antimalarial medications

- Establish appropriate mechanisms to ensure the effective distribution and uninterrupted supply of antimalarial medicines to health facilities

- Establish appropriate mechanisms for ensuring rational use of antimalarial medicines

- Establish mechanisms for monitoring the availability, quality, and appropriate use of antimalarials

METHODOLOGY

The Regional Training Course on Pharmaceutical Management for Malaria for the East and Southern African region was a five-day course designed to be highly participatory to provide an opportunity for the exchange of skills and experience among participants as an added dimension of the learning process.

The workshop sessions used a combination of the following methods—

- Presentations
- Discussions
- Group exercises
- Field activity

The training course consisted of nine sessions—

Session 0: Course Overview and Objectives
Session 1: Introduction
Session 2: Selection
Session 3: Procurement
Session 4: Quantification
Session 5: Storage, Distribution, and Inventory Management
Session 6: Quality Assurance
Session 7: Rational Medicine Use
Session 8: Monitoring and Evaluation (M&E)

RPM Plus staff members facilitated the workshop, using training course materials developed by RPM Plus. The workshop was conducted in English with French interpretation. Materials were available in both languages, and presentations were projected simultaneously in English and French. Simultaneous interpretation to and from French was provided during presentations, discussions, group exercises, and the field activity.

Participants made presentations to share experiences on particular aspects of implementing their program. Field visits were organized on the last day of the workshop to the Medical Stores Department (MSD), the Tanzania Food and Drug Administration (TFDA) Quality Control Laboratory, Mwanyanamala District Hospital, and Mnazi Moja Health Center. Participants took the opportunity to apply the knowledge gained during the course to develop and apply indicators for monitoring and evaluation of various aspects of pharmaceutical management for malaria.

A representative from the MMSS of the RBM Partnership in Geneva made a presentation on availability of ACTs and how MMSS can assist countries with their procurement processes. During the week, MMSS addressed questions and concerns from participants on procurement and its costs.

Participants worked on national improvement plans throughout the week. The plans will be used as the basis for follow-up to evaluate the course's effectiveness and to determine areas of technical assistance that may be needed to overcome any bottlenecks in the implementation process.

WORKSHOP PROCEEDINGS

Welcome and Introduction

Rima Shretta (course organizer) of RPM Plus welcomed course participants and provided a brief background on the course.

After she introduced the guests of honor, participants and partners introduced themselves. Invited guests included—

- Joseph Muhume—Chief Pharmacist, Ministry of Health, Tanzania

- Dr. Alex Mwita—Director, NMCP, Ministry of Health, Tanzania

- Pamela White—Mission Director, USAID, Tanzania

- Dr. Edwin Mung'ong'o (representing Dr. Zacharia Berege)—Guest of Honor, Director of Hospital Services, Tanzania

The Chief Pharmacist and the NMCP director both welcomed participants and visitors to Tanzania and thanked the organizers for conducting the course and USAID for providing funding.

NMCP recognized the burden of malaria in the African region as well as its challenges to malaria control and to the adoption, procurement, distribution, and promotion of rational use of ACTs by health workers.

The USAID Mission director acknowledged Tanzania's hospitality to her agency and expressed appreciation of the government's cooperation. She reminded participants of the country's malaria statistics, even after years of malaria control, and emphasized the need for a concerted effort to mobilize resources and to work together if any sort or progress is to be achieved. She acknowledged Tanzania's recommendation of ACT as first-line antimalarial treatment, though she was cautious in light of the obstacles to be overcome before those new medicines can become an effective remedy against malaria. Those obstacles include the cost of the new medicines and their special storage conditions, short shelf life, supply, and effective use. Training was highlighted as an essential component to ensure proper and effective use of the medicines. The USAID Mission director encouraged using lessons learned from Tanzania's efforts to deliver contraceptives to people who need them. She ended her remarks by restating the objective of the workshop—to enable participants to learn from one another how they can plan and implement an efficient pharmaceutical supply and management system. Tanzania is to receive 11.5 million U.S. dollar (USD) from the U.S. government for malaria control activities, and the director hoped that with the cooperation of the Tanzanian government, this support would make a substantial impact on the malaria control program.

Building on comments made by other guests, Dr. Edwin Mung'ong'o, representing Dr. Berege, the guest of honor, acknowledged that Tanzania is fortunate to benefit from support programs aimed at ensuring access to these new medicines. He acknowledged that the country recognized that funding was not the only problem facing malaria control. The rational management of medicines to achieve effective treatment means that health professionals must be trained to handle the new medicines. The initiative of RPM Plus and its collaborators to organize this course was commended because it would allow exchange of information and experiences in pharmaceutical management for the participating countries.

Plenary Presentations

Session 0. Course Overview and Objectives

Presenter: Rima Shretta

The objectives of this workshop were as follows—

- To apply appropriate criteria and select necessary first- and second- line medicines and supplies for national programs, taking into consideration the WHO recommendations

- To apply good procurement practices to antimalarial medicines

- To select an appropriate method for quantification, identify appropriate sources for data, and carry out an estimation of antimalarial medicine needs using the method selected

- To establish technical specifications and appropriate mechanisms of supply assure the quality of medications and commodities procured and used in national programs

- To establish the appropriate mechanisms to guarantee that medicines and supplies are distributed to heath services at the right time and in adequate quantities

- To establish appropriate mechanism for ensuring rational use of antimalarial medicines

- To establish monitoring mechanism for availability and use of antimalarials

The course outline and methodologies to be used in this workshop were described.

Session 1. Introduction

Presenter: Rima Shretta

This session introduced the concept of pharmaceutical management in general, and management of malaria medicines and supplies in particular, emphasizing the differences in the management of those commodities compared with others.

The pharmaceutical management cycle was used to graphically illustrate the interdependent relationships among various activities—selection, procurement, distribution, and use of malaria medicines within the existing policy and legal framework. Careful management and coordination of those activities are necessary for the cycle to function optimally. By understanding the elements of pharmaceutical management and the challenges presented by antimalarial medicines and current approaches to treatment, managers would be able to improve the efficiency of their programs, aim for the most rational use of medicines, and develop beneficial relationships with the private sector, thus ensuring availability of malaria medicines to the public. Although each country present at the course had a unique set of challenges and opportunities, the elements were generically described and could be adapted to specific country contexts.

A framework was presented on how to implement a change in malaria treatment policies to incorporate the use of ACTs.

Upon completion of this session, the participants were able to—

- Define each of the components of the pharmaceutical management cycle and its relationship to the other components

- Discuss the importance of pharmaceutical management for the success of malaria programs

- Discuss the challenges to effective antimalarial commodity management

- Discuss how the management of antimalarials differs from that of other pharmaceuticals

- Identify the effect of pharmaceutical management practices on availability and quality of malaria medicines

Plenary Discussions on Managing Medicines and Supplies

Although the world donor community had stepped up its response to the health crises by creating several global initiatives, the countries acknowledged the need to allocate funding to the fight against malaria. Burundi's response was that no specific figures could be quoted, but that this funding was a challenge concerning the whole health sector. WHO has recommended the allocation of 15 percent of government budgets to fighting malaria—in Burundi, it was 2–3 percent of the annual budget. Uganda's response was that malaria should be considered a political disease because malaria and poverty are inseparable. Uganda had set aside 10 percent of

its budget for the fight against malaria, but malaria needs a multi-pronged approach, not just money.

All participants agreed that the private sector should be involved in the implementation of ACT policies.

Group Activity

The session was followed by a group activity where the participants evaluated and identified the main problems and weaknesses their countries have in pharmaceutical management. Participants also identified the areas they would like facilitators to emphasize during the course. Plenary presentations were made by participants to provide feedback on their discussions.

Session 2. Selection

Presenter: Rima Shretta

This session focused on the process of evidence-based selection of first-line treatment policies for malaria, taking into consideration factors such as parasitic resistance to the various medicines being considered, efficacy, cost, quality, adverse effects, acceptability, and the system's management and distribution capabilities. Program managers were reminded to carefully balance need against resources and ease of implementation. In addition, recommendations from international experts such as WHO need to play part in the treatment selected.

Upon completion of this session, participants were able to—

- Discuss the basic principles of selection of appropriate essential antimalarial medicines

- Define the WHO's recommendations for treatment of *P. falciparum* and *P. vivax* malaria

- Discuss the process of selection of first- and second-line treatments for malaria

- Discuss the challenges for selection of first- and second-line antimalarial treatments

- Define essential medicines lists and standard treatment guidelines (STGs) and their relationship to each other

Plenary Discussions on Selection

Some participants felt that the efficacy of artemisinins in Africa could not be compared to their efficacy in Asia because of different malaria epidemiological patterns. They cautioned against the indiscriminate use of crude artemisinin preparations in Africa (boiling leaves and drinking the fluid for malaria treatment) that might adversely affect the efficacy of ACTs and advised countries to consider introducing regulations to ensure such use does not happen. It was resolved that introducing regulations on artemisinin cultivation may make it more desirable or valuable. A

more appropriate approach might be to educate the public that boiling artemisinin leaves when they have malaria will not provide a cure because of the insolubility of artemisinin.

There was some discussion on intermittent preventive therapy (IPT) for prevention of malaria during pregnancy. Some countries, such as Burundi, are unable to use sulfadoxine-pyrimethamine (SP) for IPT because of the resistance developed to its use during application of the previous policy. Because there is no current replacement for IPT, a gap exists in the policy for prevention of malaria in pregnancy. Adverse drug reactions (ADRs) to SP were also seen as a problem and present an urgent need for development of new alternatives. The viability of using herbal medicines as possible alternatives was proposed for investigation (however none of these have been certified as efficacious or safe for use during pregnancy to prevent malaria).

Regarding quinine as a second-line treatment option, although quinine is already used in most countries, a need was mentioned to reevaluate its clinical efficacy for the treatment of severe complicated malaria.

It was proposed that the legal framework within countries should be used to combat the production, distribution, sale, and use of counterfeit medicines. This action would protect counterfeiting of artemether-lumefantrine (Coartem®) and other ACTs.

The effectiveness of rapid diagnostic tests (RDTs) was queried by some participants. Participants were reminded that the issue was not just the effectiveness of RDTs but whether they were cost-effective. Countries must decide individually whether or not to adopt them in place of clinical diagnosis; no general recommendations were made. Studies in Rwanda were reported to have shown no significant difference between RDTs and clinical diagnosis, so the recommendation is that RDTs be used only in epidemics. Furthermore, WHO recommended that in endemic countries in Africa, RDTs should be used only for diagnosing adults and clinical diagnosis should remain the mainstay of malaria diagnosis in children.

The use of ACTs for mass administration campaigns to clear the parasites from population was proposed. This was reported to have previously tried during the chloroquine and malaria eradication era without success.

Burundi and Madagascar—Experiences with Antimalarial Medicine Policy Change and Selection of First- and Second-Line Treatment

Background information was provided on malaria epidemiology in Burundi. The first-line treatment is amodiaquine + artesunate, while quinine is the second-line antimalarial. For treatment of severe malaria, quinine is used. No medicine is currently available for IPT. The current policy was adopted in November 2003. Until June 2001, SP was the first-line antimalarial while quinine was reserved for second-line treatment and for the treatment of severe malaria. SP was used for IPT.

Experiences with implementation of the policy were shared as well as the major challenges faced and interventions that had worked. The major challenge with the use of amodiaquine + artesunate in Burundi was low compliance caused by nausea and vomiting. With close

supervision, this problem was overcome. The adverse effect was discovered to be caused by the first dose only; so that was administered at the health center before the patient left for home. Subsequently, other health workers were trained on how to improve compliance, and there are no problems with the new protocol.

In Madagascar, malaria is the leading cause of mortality and the the most frequent reason for medical consultation. In the previous protocol, chloroquine was available for simple cases and for pregnant women while quinine was available for severe cases. SP was available as a second-line antimalarial. A survey of resistance patterns to chloroquine had shown that resistance had risen to 20–25 percent. The first step to changing the policy was to get support from politicians and donors and then a new malaria treatment policy was formulated and adopted. An efficacy study was conducted and no resistance was observed during the study.

The policy is currently as follows—

- The first-line antimalarial is now artesunate + amodiaquine
- The second-line medicine is artemether-lumefantrine
- For severe cases quinine is used
- For IPT, SP is used

After adopting the new policy, the program was piloted in 21 districts. Trainers were trained, followed by training of pharmacists. Medicines were then procured, and the program was implemented, evaluated, and rolled out. A pharmacovigilance program was put in place. During the transition, chloroquine remained available. With respect to diagnosis, a study indicated that RDTs showed an effectiveness of 15 percent of clinically positive patients.

Session 3. Procurement

Presenter: Francis Aboagye-Nyame

This session reviewed the standard methods of the procurement process and the resources (organizational components) that a supply system must have to procure medicines and supplies at the lowest possible total cost.

The session outlined some procurement processes and requirements of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), particularly in relation to how they affect national-level procurement of ACTs and other related antimalarials (procured using GFATM resources).

By the end of the session, participants were able to—

- Identify and describe the steps in the procurement cycle

- Compare the advantages and disadvantages of the four alternatives for purchasing medicines

- Recognize the characteristics of a good pharmaceutical procurement system

- Identify potential problems in accepting medicine donations

- Discuss challenges in procuring malaria supplies

Kenya—Experience with GFATM Procurement Procedures

A background of the malaria prevalence and the malaria policy was presented. Kenya announced a policy shift from SP to ACTs in 2004, and the country is currently in the initial stages of implementing this policy.

Funding for the procurement of all GFATM commodities, including medicines and supplies for the new policy, is being handled by a procurement consortium (funded by USAID in the amount of USD one million for three years). The contract for this support was signed in February 2004. ACTs are being procured directly from Novartis, and award decisions have been validated by the Ministerial Tender Board.

The main challenge faced with GFATM procurement procedures is that the contract took too long to negotiate. It was necessary to adhere to both the Government of Kenya and USAID procurement regulations, which slowed down the process.

The main opportunities include—

- The Kenya Essential Medical Supplies Agency is making the procurement process operational

- MMSS will assist in procuring Coartem

- Technical assistance is being obtained from a consortium of partners such as Crown Agents and GTZ

- A new, more transparent, and flexible procurement law was passed in September 2005

MMSS and the RBM Partnership—Availability of ACTs and Related Procurement Issues

Presenter: Rémy Prohom

The clinical needs that should be considered in choosing ACTs as well as the rationale for ACT use were discussed. WHO-recommended combination therapies were presented, and details such as indication for use, manufacturers and cost, buffer stock, and future capacity were provided on artemether-lumefantrine, artesunate + amodiaquine, artesunate + SP, and artesunate + mefloquine.

Participants were informed that although the production of ACTs has been increased to meet growing demand, the importance of taking delivery lead-time of into consideration when ordering ACTs is paramount. The importance of proper storage of ACTs was also highlighted.

Group Activity

The session was followed by a country activity during which countries started working on their national improvement plans.

Session 4. Quantification

Presenter: Francis Aboagye-Nyame

This session outlined the rationale for quantification of antimalarials and identified the methods commonly used for quantification and the data needed. It also looked at the particular issues related to malaria medicine quantification. The four commonly used quantification methods—morbidity, consumption, adjusted consumption, and service-level extrapolation—were described in detail, with discussions on the principles underlying the choice and use of the various methods. Changing treatment policies must take into consideration essential data sources for each quantification method and the weaknesses of the various types of data together with the challenges to the quantification of antimalarials in the context of, including the assumptions that need to be made in the practical execution of the quantification process.

Participants practiced using examples until they grasped concepts.

By the end of the session, participants were able to—

- Outline the rationale for quantification of antimalarials

- Identify four methods commonly used in the pharmaceutical quantification process and describe their uses, strengths, and limitations

- Recognize data needed to conduct the quantification

- Discuss particular issues related to malaria medicine quantification, including the assumptions that must be made

- Outline the steps for using the consumption and morbidity methods

- Practice the morbidity and consumption-based methods

Plenary Discussions on Quantification

It was agreed that proper planning is necessary to prevent wastage of medicines as policies are changed.

When national estimates were unavailable, it would be advisable to quantify needs for individual districts or units and pool them together. There was some discussion on quantification of medicines for IPT and the use of crude birth rate to calculate those requirements.

The electronic tool Quantimed, developed by RPM Plus, was requested for use by the countries. The countries will receive feedback on the possibility of acquiring Quantimed and being trained to use it by RPM Plus.

Interventions to prevent leakage were discussed. In Zanzibar, ACTs intended for public health facilities were stamped with a logo. This method was helpful to an extent but did not prevent leakage altogether. The stamping or branding could be done by the manufacturer; however, this process may increase the cost of the medicines. Other preventive measures include the balancing of supply and demand, and the use of differently colored tablets or capsules.

There was some discussion on the use of weight versus age for calculating dosages. The morbidity method of quantification uses age stratification; however, some country's STGs (e.g., Ethiopia) outline treatment by weight. Participants inquired about converting weight requirements into age stratification during the quantification process. It was agreed that it would be more important to focus on number of patients treated with a particular regimen.

Session 5. Storage, Distribution, and Inventory Management

Presenter: Kathy Webb

This session discussed the elements in a distribution system—including its design (centralized or decentralized), the information system, the storage conditions, the delivery mechanism, and inventory management—and analyzed each of those elements while discussing a variety of options for improving the efficiency of the entire system.

By the end of the session participants were able to—

- Discuss the various components of the distribution cycle

- Discuss the principles of good storage, distribution, and inventory management

- Identify the inefficiencies in participants' distribution, storage, and inventory management systems

- Discuss alternatives for improving the efficiency of storage, distribution, and inventory management systems

- Calculate and discuss inconsistencies between physical inventory and recorded quantities

Plenary Discussions on Storage, Distribution, and Inventory Management

Some countries have extreme ambient temperatures of above 30°C and the recommended storage temperature of ACTs is 25°C, so they must be stored in cooler areas and in original packaging to prevent problems with humidity. High temperatures are also deleterious for RDTs. There was some discussion on the definition of a full supply pipeline, which means availability of the reserve supply required for the given number of months during which the next stock is being processed for the given facility. A full supply item is an item that should be in supply all the time.

The ministries were criticized for omitting the private sector in distributing ACTs because the private sector handles a considerable portion of the patient load. It was suggested that a resolution to address this anomaly should be drawn up. The GFATM encourages countries to develop proposals to incorporate the private sector. However, no country present at the meeting had proposed to take the private sector into consideration. Manufacturers should be convinced to change their policies to embrace preferential prices for both public and private sectors.

Democratic Republic of Congo—Experience with Parallel Distribution Systems

The presentation began with some background information about DRC. The history of procurement in DRC can be traced back to the colonial era, during which the Belgian plan procured and distributed medicines free of charge to the public. In 1945, medicines were procured by the Central Medical Stores but free distribution continued. With independence in 1960, the government became more involved in distributing medicines to its people. With the Bamako Initiative about 1996, the private sector became involved.

Strengthening of distribution in the private sector came from nongovernmental organizations (NGOs) and United Nation's agencies.

Vertical programs for diseases such as leprosy, AIDS, and trypanosomiasis were supported directly from outside. Each donor identified the health zone that it felt was most needy.

Two types of private distributors of medicines exist in the DRC—the not-for-profit NGOs and those that operate commercially. In Kinshasa alone, about 50 private stores are involved in distributing medicines. Some private firms are also doing local manufacturing of medicines.

The consequences of parallel distribution are that the geographical coverage is unequal in the different zones. A diversity of administrative structures exists as well as differences in quality and prices. Pharmacovigilance measures are difficult to introduce.

To redress the situation, procurement has been centralized, but distribution to regional centers has been decentralized. Suppliers now must be prequalified. Training on medicine management has been undertaken and the quality assurance system has been strengthened.

Health facilities identify needs through the regions (Centre de Distribution Régional) and these are organized and coordinated by the Fédération des Centrales d'Approvisionnement en

Médicaments Essentiels (FEDECAME). FEDECAME compiles the tender documents and harmonizes procedures for tendering, monitoring, and follow-up.

Plans exist to divide the country into 40 centers, each of which will comprise about 1.5 million people, thus effectively covering the 65 million people in DRC. Plans also exist to involve the private sector by getting them to sign a contract with the government to provide distribution services. Subsidized services are expected to increase coverage.

Private pharmacies get their supplies from the importation system and private wholesalers.

In DRC, the illegal sale of medicines coupled with sale of substandard medicines is a real problem. The regulatory authority in DRC is understaffed and is ill-placed to effectively control the pharmaceutical sector. This problem is worsened by DRC's porous borders. It is hoped that neighboring countries of DRC will strengthen medicine regulation so that the medicines reaching DRC, most of which pass through those countries, will be of assured quality.

Zambia—Experience with Implementation

High resistance levels to chloroquine (40–50 percent) in all nine provinces caused the Zambian government to adopt a new policy in 2002 that recommended the use of artemether-lumefantrine. The new policy was developed taking into account the available data on malaria parasite resistance, the medicines currently available, and their role in managing malaria. The presentation outlined the steps that Zambia took toward implementation.

Zambia's new policy was implemented in phases, starting with nine sentinel districts in 2003. Coverage was scaled up to the entire country by April 2004.

The issues now faced by Zambia following implementation include—

- The cost implications of treatment and its sustainability

- The gap in availability of treatment in private sector and at community levels, insufficient diagnostic capacity

- Deficiencies in the health management information system

- Availability of ACTs in second- and third-level hospitals in the first year of implementation

- Problems in integrating the program in the country's Logistics Management Information System

Group Activity

This session was followed by a group activity session to monitor inventory management and ascertain stock-outs.

Session 6. Quality Assurance

Presenter: Rima Shretta

In this session, quality assurance and the different approaches to it were clarified. The session expanded the participants' awareness of global concerns regarding the use of substandard pharmaceuticals and the cause of their proliferation as well as the determinants of pharmaceutical quality. It emphasized both the technical and managerial actions that can be used to ensure pharmaceutical quality.

After completing this session, participants are able to—

- Specify what is meant by quality assurance and quality control in managing the supply of antimalarials and identify the factors that affect their quality

- Describe the components of a comprehensive quality assurance program and practical framework at different levels of responsibility

- Identify practical technical and managerial approaches and procedures to ensure pharmaceutical quality in daily activities

Plenary Discussions on Quality Assurance

There was some discussion on expiry dates for infusions and other injectable medicines. It was noted that for sterile products expiry also means loss of sterility.

There was a request for examples from countries with established quality assurance. The organizers informed the participants that Tanzania had set up such a system and there would be a presentation on the Tanzanian experience with the quality assurance system.

There was a request made for information on the minilab test kits. The price was stated to be USD 4,500 per kit.

Participants encouraged WHO to prequalify both international and local ACT manufacturers.

The problems of poor quality medicines in African countries were said to be mostly caused by weak regulatory authorities. Participants advocated for WHO to extend the quality control surveys to other countries so that their results could be used to convince governments to strengthen regulatory authorities. For a country like the DRC, which has nine common borders with other countries, convincing governments to strengthen regulatory authorities is paramount as this would go a long way to assuring the quality of medicines coming into DRC through bordering countries. Countries were encouraged to carry out testing themselves. Assistance on how to undertake the studies can be obtained from the local WHO offices. It was noted that ACT reference standards have not yet been developed.

In the follow-up after training, there was some discussion on the fact that WHO had conducted many training sessions on good manufacturing practices (GMP), but if countries do not apply them, GMP would have no positive effect.

Group Activity

During this group activity participants described the current systems of quality assurance/quality control for antimalarials implemented under their current malaria program.

Tanzania Food and Drug Administration—Improved Regulation and Quality Assurance of Medicine

Presenter: Mr. Adelard Mtenga

The presentation detailed the drug regulatory functions of the TFDA, which include drug registration; pre-registration GMP inspection; postmarketing surveillance; registration and licensing of pharmaceutical manufacturers, importers, and distributors; control of importation and exportation; drug quality control; and monitoring of ADRs.

Drug registration documents are assessed by TFDA staff members and a panel of external experts. Documents are assessed on a first-in/first-out basis, and it takes about 12 months to register a product. However, a fast-track system of three months for registration (if there are no queries) exists for antimalarials, ARVs, and TB medicines. Standard Operating Procedures are being finalized to increase efficiency and effectiveness.

The TFDA laboratory was established in 2000 and has the capacity to handle most of the analytical work. In certain instances, work is contracted out to other labs. It is now moving toward accreditation and is in the process of becoming WHO prequalified.

The presentation went through the technical requirements necessary for registration and GMP inspections. The TFDA has fully registered 3,446 drug products, and 272 local facilities have been given provisional registration since its inception.

A drug quality assurance program was launched in 2002, with technical assistance from MSH-SEAM and using German Pharma Health Fund-Minilab® kits developed for the purpose of screening pharmaceuticals (both imported and produced locally) quickly using simple thin-layer chromatography (TLC) techniques. This program aims to strengthen post marketing surveillance. The TFDA has focused on inspection and testing of drugs at the major ports of entry and the Medical Stores Department. Ten TLC minilab screening sites have been established for targeted antimalarials, antibiotics, and antiretroviral drugs.

There are 329 trained inspectors. Inspectors use portable digital assistants (PDAs) that are loaded with the list of registered products and suppliers, registered and licensed premises, and pro forma invoice data. The PDA helps verify whether products being imported are registered and had prior approval for importation. The product information is quickly sent back and downloaded to the database at TFDA headquarters. Point-of-entry inspectors physically inspect consignments.

An achievement of the quality assurance program is that the number of substandard products in the market has been substantially reduced, from 13 percent in 2001 to 3.7 percent of 1,257 products sampled in 2005

TFDA is also responsible for monitoring ADRs. Prepaid reporting forms have been developed and circulated to hospital health care workers. Any reports are assessed by an expert committee that recommends the appropriate regulatory action. Guidelines for monitoring and reporting ADRs will be published soon, and assessment of the performance of drug information centers in four referral hospitals that was carried out in 2004–2005 is being finalized.

Session 7. Rational Medicine Use

Presenter: Gladys Tetteh

This session covered how appropriate mechanisms for ensuring rational antimalarial medicine use may be established. It described the medicine use processes from diagnosis to prescribing, dispensing, and patient use and the problems experienced with antimalarials at each level. It also described the factors influencing antimalarial use and discussed appropriate interventions to improve antimalarial medicine use.

After completing this session, participants were able to—

- Define rational use
- Discuss the factors affecting use of antimalarials
- Discuss and apply methods to identify these problems
- Identify effective strategies to promote rational use of antimalarials

Plenary Discussions on Rational Medicine Use

Participants commented that prescribing antimalarials using clinical diagnosis may result in wastages. Mr. Prohom (MMSS) informed participants that information on lists of suppliers of RDTs and the prices they offer were available and could be provided to interested countries.

The need to train dispensers properly on how to use ACTs correctly was stressed as necessary in ensuring that patients in turn would understand how to use ACTs effectively.

It was mentioned that rational medicine use requires accurate diagnosis using either microscopes or RDTs and purchase of these items was justifiable. The cost of one RDT is about USD 1 compared to the the cost of ACT which is about USD 10. If RDTs were used, about 40 percent of cases that would otherwise be diagnosed malaria-positive could be ruled out, thus avoiding inappropriate use of ACTs and provide considerable savings. A positive confirmation of malaria infection by microscope or RDT did not necessarily mean that the severity of a patient's symptoms was caused by malaria because it could be caused by a simultaneous bacterial or other infection.

It was agreed that a need exists to consolidate the use of microscopes since they are widely available in health facilities but are underused for lack of necessary reagents or personnel.

It was suggested that a simplification of the dosage regimen for Coartem from the current adult dose of 4 tablets to start followed by 4 tablets after 8 hours, another 4 tablets after 24 hours, and finally 4 tablets after 48 hours would ensure rational use. It was also suggested that using double-strength tablets would help reduce the quantity of tablets taken.

Group Activity

A case study that provided a scenario on rational medicine use for malaria was given to participants. The participants worked together to respond to various questions posed at the end of the scenario. Some examples of responses were provided to participants at the end of the session.

Uganda—Experience with Home-Based Management

Uganda's goal is that by 2010 at least 80 percent of patients suffering from malaria get the right treatment in their communities within 24 hours. The strategy adopted was to use home-based management. Implementation included changing behavior, prepackaging the first-line antimalarials, and distributing them to community level. Voluntary Community Medicine Distributors (CMDs) were recruited in the villages. They were then trained on the purpose of the program, storage techniques, recording, diagnosing malaria, dispensing, and monitoring of ADRs.

Strategies used to ensure that the program worked included—

- Educating health workers that home-based care was conceived of as complementing rather than replacing their services

- Training, supervising, and monitoring the CMDs

- Educating CMDs that their role was to complement (not to replace) the health workers and that they were accountable to the health workers

- Having villagers select candidates to become CMDs

- Maintaining primary school standard level seven as the minimum education level required of potential CMDs

- Instituting a three-day training that started with establishing the knowledge gaps

- Providing incentives to CMDs to prevent attrition

- Using behavioral change campaigns and appropriate communication to discourage concomitant use of herbs and orthodox medicines

- Providing Ministry of Health financing

The success of the home-based care malaria program was demonstrated by a substantial reduction in clinic visits by children under the age of five—the population most affected by malaria. The case fatality rate for this age group was reduced from 5 to 3 percent, anemia reduced from 20 to 13 percent, and 63 percent of children had access to first-line antimalarials within 24 hours at community level. The program covered all of Uganda.

Malaria treatment with Coartem is to start in the near future. Uganda expressed confidence that donor funding would sustain the project, and in the event that this funding was not available, the Government of Uganda should be able to find alternative ways of financing it because it was fulfilling an important function in society.

Session 8. Monitoring and Evaluation

Presenter: Gladys Tetteh

This session described how, when, and why to monitor the performance of the pharmaceutical management system for malaria. The session briefly covered assessment or diagnosis of pharmaceutical management systems and also provided an overview of methodologies used to evaluate the effect of interventions and the effectiveness of their implementation. The main focus was on monitoring and improving performance through indicator-based methods, supportive supervision, on-the-job training, and capacity building.

After completing this session, participants were able to—

- Differentiate between monitoring and evaluation

- Describe performance monitoring

- Describe the performance improvement process

- Provide information on methods to monitor performance and evaluate the effect of pharmaceutical management interventions

- Identify key performance indicators for monitoring management of malaria medicines and pharmaceutical supplies

- Elaborate on the use of monitoring systems in improving performance of the malaria pharmaceutical management system and evaluate the effect of pharmaceutical management interventions

- Evaluate the quality of the data

- Have an opportunity to become familiar with the concepts of performance monitoring and evaluation through group exercises and fieldwork

Plenary Discussions on Monitoring and Evaluation

Individual countries were at liberty to adapt the sample targets provided according to their own situations. Participants felt that support to developing countries by the global donor community had not focused on developing management information systems; therefore this particular area is weak and unreliable in African countries. Furthermore, there were too many data collection formats and were too confusing.

Field Exercise

Participants conducted a field exercise during which they selected indicators, prepared instruments, and collected data. This exercise was to challenge participants to think critically about the performance of pharmaceutical management systems and the data that can be collected to make decisions regarding selection, procurement, distribution, availability, and use of antimalarial medicines.

Interpreters were available to assist the French-speaking participants.

Procurement at Medical Stores Department

Indicators used in assessing the procurement of medicines in the visited site included—

- Time of delivery for the last three consignments
- Time of approval of orders
- Cost of antimalarial medicines
- Distribution—quarterly period
- Stock control

MSD operates a USD 100 million budget and has a staff capacity of 300. MSD procures 80 percent of its medicines from the international market and 20 percent locally. An open international tendering process is used. MSD has four big stores in Dar es Salaam and seven zones with their own stores. Management of stocks is fully computerized. The number of clients is 5,000, the majority of which are health centers, dispensaries, and hospitals. Stock control uses no manual cards.

Quality Assurance at the Tanzania Food and Drugs Authority

The functioning of TFDA was explained, and there was a guided visit of the laboratory.

TFDA had a small but sufficiently equipped laboratory. The agency has a data bank with reliable data.

Tanzania has not started to implement the ACT policy. Between 1999 and 2005, 28.32 percent of antimalarials being marketed in the country were unregistered. The number of antimalarials that had to be recalled for failed quality standards was 3.7 percent (data for one year). All medicines

being marketed in the country had to undergo a registration process that included laboratory analysis of samples. Inspection is part of surveillance.

TFDA has a good quality assurance system in place and is poised to realize its 2010 vision of becoming a center of excellence in medicine regulation in sub-Saharan Africa. It was noted that even for a country such as Tanzania, which has a good quality assurance system in place, counterfeit medicines are still a challenge. Authorities need to be cognizant of the challenge of counterfeits and take more stringent steps to protect the public.

Field Visit to Mwanayamala District Hospital

Five indicators and a checklist for the assessment were developed.

Almost all the medicines assessed had no proper records. There were no bin cards for SP and quinine tablets. A ledger was available for quinine injection but the figures did not tally. The pharmacist-in-charge explained that he was collecting and issuing medicines without holding any stocks. The percentage of expired antimalarial medicines was 41 percent.

The district hospital had no reliable data in the store on which to base decisions. Expired stocks were kept on shelves instead of in a separate warehouse. There was no system of keeping bin cards near the product; rather, they were kept on the pharmacist-in-charge's desk.

There was a clear need to enhance supervision at this particular facility.

Assessment of Pharmaceutical Management for Malaria in Mnazi Mmoja Health Center

The assessment was based on five antimalarials (SP, quinine, amodiaquine, chloroquine, and ACTs). Some of the indicators included rational medicine use, record keeping, and medicine use counseling.

Background information on the Mnazi Mmoja Health Center was provided. In operation for 30 years, the center has a medical officer in charge. Medicines are received from a district store and the health center store is in a good state of maintenance. The top 10 diseases treated at the center included malaria, HIV/AIDS, worms, and skin infections. STGs were available, including those for malaria.

Bin cards were available for antimalarials. Five cards existed and were up to date, indicating 100 percent results for this indicator.

The percentage of patients who could correctly describe how to take the prescribed medicines was assessed. It was reported that seven patients had been interviewed and only one could not describe correctly how to use the medicine, so the result was 87.5 percent compliance.

The percentage of prescriptions that were consistent with STGs was also assessed. Ten prescriptions were examined and all were consistent with the STGs (100 percent compliance).

Other observations—

- Medicine records were up to date
- Bin cards were properly kept
- Air conditioning in the store was good
- A shortage of storage space existed and shelves were inadequate
- The dispensing area was congested and made patient counseling a challenge

Participants recommended that the store and dispensing area be enlarged.

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ANNEX 2. COURSE AGENDA

Day	Time	Activity	Presenter/Facilitator
Day 1	9:00–9:15	Welcome	
	9:15–9:45	Opening of the course	Tanzania Ministry of Health representative; USAID Tanzania Mission representative
	9:45–10:15	Introduction of presenters and participants	
	10:15–10:30	**Break**	
	10:30–11:00	Introduction and format of the course, formation of groups, rules, daily evaluation, logistics	
	11:00–12:15	**Session 1.** Introduction to Management of Malaria Medicines and Supplies	Rima Shretta, MSH/RPM Plus
	12:15–13:00	Group Activity (Worksheet 1.1)	
	13:00–14:00	**Lunch**	
	14:00–14:30	Presentation of Group Activity (2 groups)	Group presentations
	14:30–15:45	**Session 2.** Selection	Rima Shretta, MSH/RPM Plus
	15:45–16:00	**Break**	
	16:00–17:00	Experiences with antimalarial medicine policy change and selection of first- and second-line treatment	Burundi; Madagascar
Day 2	8:30–8:45	Plenary (questions and clarifications)	
	8:45–10:30	**Session 3.** Procurement	Francis Nyame, MSH/RPM Plus
	10:30–10:45	**Break**	
	10:45–11:00	Experience with GFATM procurement procedures	Kenya
	11:00–13:00	Group Activity (Worksheet 3.1 Begin National Improvement Plan, country groupings)	
	13:00–14:00	**Lunch**	
	14:00–14:45	Availability of ACTs and other procurement issues	Rémy Prohom, Malaria Medicines and Supplies Service, WHO
	14:45–16:15	**Session 4.** Quantification	Francis Nyame, MSH/RPM Plus
	16:15–16:30	**Break**	
	16:30–18:00	Group Activity (Worksheets 4.1 and 4.2)	

Day	Time	Activity	Presenter/Facilitator
Day 3	8:30–8:45	Plenary (questions and clarifications)	
	8:45–9:00	Presentation of group activity (2 groups)	Group presentations
	9:00–10:30	**Session 5**. Storage, Distribution, and Inventory Management	Kathy Webb, MSH/RPM Plus
	10:30–10:45	**Break**	
	10:45–11:00	Experience with parallel distribution system	DRC
	11:00–11:30	Experience with implementation	Zambia
	11:30–13:00	Group Activity (Worksheet 5.1)	
	13:00–14:00	**Lunch**	
	14:00–16:00	**Session 6.** Quality Assurance	Rima Shretta, MSH/RPM Plus
	16:00–16:15	**Break**	
	16:15–16:30	Group Activity (Worksheet 6.1)	
	16:30–17:30	Experience with improving regulation and quality assurance	Tanzania Food and Drug Administration (TFDA)
Day 4	8:30–8:45	Plenary (questions and clarifications)	
	8:45–10:00	**Session 7.** Rational Medicine Use	Gladys Tetteh, MSH/RPM Plus
	10:00–10:15	**Break**	
	10:15–11:15	Group Activity (Worksheet 7.1)	
	11:15–11:30	Experience with home-based management	Uganda
	11:30–13:00	Continue to work on National Improvement Plan (country groupings)	
	13:00–14:00	**Lunch**	
	14:00–15:30	**Session 8.** Monitoring and Evaluation	Gladys Tetteh, MSH/RPM Plus
	15:30–16:00	Instructions for the monitoring and evaluation exercise (Worksheet 8.1)	
	16:00–16:15	**Break**	
	16:15–17:30	Group Activity (Worksheet 8.1, preparation for fieldwork)	

Day	Time	Activity	Presenter/Facilitator
Day 5	8:30	Depart hotel for field visits (participants must be ready at 8:15 for a prompt 8:30 departure)	
	9:00–12:00	Fieldwork	
	12:30–13:30	Group Activity (Worksheet 8.1, preparation for presentation)	
	13:30–14:00	Lunch	
	14:00–15:00	Presentation of group activity	Group presentations
	15:00–15:15	**Break**	
	15:15–16:45	Continue to work on National Improvement Plan (country groupings to be submitted to facilitators at the end of the day)	
	16:45–17:00	Closing Remarks	

ANNEX 3. GROUP PRESENTATIONS

Participants were divided into four groups to take stock of problems they face in their own countries with respect to the pharmaceutical management cycle.

Zambia and Rwanda

Policy and Legal Framework

The group encountered difficulties in building consensus for change because there was inadequate data to convince people to accept the proposed changes. There was also a shortage of health care workers and many of these workers are untrained. The information system was unreliable to ensure effective rollout.

Selection

A long lag period was experienced between announcement of the new policy and preparation of STGs. Morbidity data were unreliable and quantification was not properly coordinated.

Distribution

The private sector was left out, exposing the program to possible pilferage problems. Availability of Coartem was limited to only certain facilities, thus not functioning as a proper first-line treatment. The group emphasized the need to institute medicine use evaluation.

Management Support

The main concern raised here was sustainability and incorporation of second-line medicines.

Plenary Discussions

- Private Sector—It was noted that the private sector did not adhere to the national protocol or standard treatment guidelines for malaria.

- Funding—There are no funds for training or follow-up.

- Quantification—This is not uniform through the different levels of health care.

- Pharmacovigilance—This is not done.

- It was recommended that National Medicines List should be updated to include ACTs. There is no drug registration system in Rwanda.

- Resistance to policy change—in Zambia, there was strong resistance initially, particularly from the technical fraternity. In contrast, in Zanzibar the pressure for change came from the

community itself. The politicians and health personnel also supported the change because chloroquine had completely failed to cope with malaria, making everybody ready for change.

DRC and Burundi

The participants from Burundi reported the inadequacy of regulations and the failure to update the STGs. They reemphasized the need to involve both the public and private sector.

Management Support

The national structures were not involved and the community participated only slightly. There are also difficulties in estimating needs.

Financing

There are insufficient resources and weak financing from national point of view, and financing is mainly donor dependent.

Training

Training is inadequate.

Selection

It is unclear what criteria were used to make the selection.

Procurement

There was insufficient involvement of structures. There were also delays in supplies and inadequate coordination. WHO guidelines were not followed, particularly in DRC.

Use

Information systems are nonexistent. Good Dispensing Practices are not followed and a phamacovigilance system is not in place.

Tanzania Mainland and Uganda

Unregistered drugs are in use. Medicines are not uniformly available in all levels of the health system. Affordability is a major problem. Medicine selection may suffer from political influence.

Procurement

Delays are experienced because of different bodies being responsible for procurement, which leads to frequent stock-outs. Consumption and morbidity data are insufficient to support accurate quantification of needs, which could lead to wrong projections. The team recognized that training in medicine management systems should be given priority.

Distribution

Transportation was identified as the main constraint, especially from the main stores to substores. There is also a lack of adequate storage facilities. The use of common transportation systems, for instance those used for vaccines and medicines, was suggested.

Use

Noncompliance as well as administration or prescribing of wrong doses caused by inadequate training was reported. Education and training were identified as a way to resolve this issue. An example was given of such an effort conducted in Rufiji (Tanzania) for health workers and community members. Another approach suggested was to introduce community outreach programs to educate people in remote areas.

Financing

The main problem has been limited budgets allocated to the fight against malaria, such as only 10 percent of the health budget was allocated in Uganda. This was attributed to inadequate political support.